

Frequent issues regarding shipments to Saudi Arabia

For any information regarding

The Regulation and Requirements for Clearance and Export

**Regulations of Transporting and Storing Medication and
Pharmaceutical products through Customs Ports**

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- **NON- Compliance with Saudi FDA Regulations of Transporting and Storing Medication and Pharmaceutical products through Customs Ports: (like the following)**
 - Transporting in a non-temperature controlled containers.
 - Transport and Storing conditions are not suitable for the shipped products.
 - Not placing the required amount of data loggers in the shipment.
 - Using Data Loggers that does not comply with SFDA specification for data loggers.
 - Placing a Data Loggers without activation.
 - Stoppage of the Data Loggers recording before shipment arrival to the agent warehouse.
 - **NON- Compliance with Saudi FDA Clearance Requirements:**
 - **Issues regarding the outer pack, like not printing the following:**
 - Saudi registration number and public price (IN ARABIC.) ⁽¹⁾
 - Products information (IN ARABIC). ⁽¹⁾
 - Storage conditions (IN ARABIC). ⁽¹⁾
 - Manufacturing company name and nationality. ⁽¹⁾
 - Manufacturing and expiry date according to The GCC Guidance for Presenting the SPC, PIL and Labeling Information. ⁽¹⁾
 - (FOR ANIMAL USE ONLY) on the outer pack for the veterinary medications (IN ARABIC). ⁽¹⁾
 - The phrase (Free medical samples) on the outer pack for the products that intended for medical samples (IN ARABIC). ⁽¹⁾
 - **The non-compliance with the following:**
 - Tamper proof and plastic sealed cap for the liquids plastic and glass bottle.
 - Label Information on the outer pack as specified by SFDA.
 - Manufacturing or marketing company invoice requirements.
 - Printed price and/or Shelf life on the outer pack does not match what registered in SFDA ⁽¹⁾.
 - Printing the data logger's serial numbers in one of the shipment documents.
- ❖ **The issues mentioned above, may result in shipment delay or rejection the clearance.**

(1) This requirement is for products registered in Saudi Arabia only.